NHS
National Patient Safety Agency

Patient safety alert

03

Alert

29 July 2004

Reducing the harm caused by oral methotrexate

Oral methotrexate is a safe and effective medication if taken at the right dose and with appropriate monitoring. However, the NPSA is aware of 137 patient safety incidents over the last ten years in England alone due to problems with taking the medication. This includes 25 patient deaths and 26 cases of serious harm.

Action for the NHS

NHS acute trusts, primary care organisations and local health boards in England and Wales should take the following steps by March 2005:

1 **Agree local action required**
Agree appropriate local risk reduction actions through your Drugs/Medicines and Therapeutic Committee.

2 **Provide patient information before and during treatment**
Recommended core content for a pre-treatment information leaflet provided before treatment starts and a patient-held monitoring and dosage record during treatment is attached to this alert.

3 **Update prescribing and dispensing software programmes**
All prescribing and dispensing software programmes in primary and secondary care locations must be updated with the latest software which includes methotrexate alerts and prompts.

4 **Review purchasing**
Purchasers of 2.5mg and 10mg tablets should ensure that the tablets are visually distinguishable by shape, and that packaging contains the cautionary wording required by the Medicines and Healthcare products Regulatory Agency.

For response by:

- NHS acute trusts and primary care organisations in England and Wales

For action by:

- Medical directors in England and Wales

We recommend you also inform:

- Clinical governance leads
- Clinical leads for rheumatology and dermatology
- Risk managers
- Directors of nursing
- Chief pharmacists/pharmaceutical advisers
- Heads of IT
- Communications leads
- Patient advice and liaison service staff in England
- Procurement managers

The NPSA has informed:

- Chief executives of acute trusts and primary care organisations in England and Wales
- Chief executives/regional directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales)
- Medicines and Healthcare products Regulatory Agency
- The Healthcare Commission
- Healthcare Inspectorate Wales
- NHS Purchasing and Supply Agency
- Welsh Health Supplies
- Royal colleges and societies
- Methotrexate manufacturing or licence holder companies
- Prescribing and dispensing IT system suppliers
- NHS Direct
- Relevant patient organisations and community health councils in Wales
- The Independent Healthcare Forum

Further information on the action points

1 Agree local action required

A review should be undertaken, through Drugs/Medicines and Therapeutics Committees, of the shared care arrangements for prescribing and monitoring oral methotrexate in rheumatology and dermatology and other clinical areas using once weekly methotrexate. Representatives from clinical teams, pharmacy, risk management, IT and communications should be included in the review as appropriate.

2 Provide patient information before and during treatment

The Committee should reproduce the pre-treatment information leaflet and patient-held monitoring and dosage record using the guidelines and core content in the attached insert. All patients receiving oral methotrexate therapy either initiated by specialist clinics or continued through general practice/primary care prescribing should receive both documents.

The Committee can include local information such as contacts and helpline details, and any additional information prompted by local concerns. Any additions should not replace the core content unless clinical knowledge changes.

The documents should be available to all relevant clinicians and in use by March 2005.

3 Update prescribing and dispensing software programmes

The NPSA has worked with major database and system suppliers to ensure that safety enhancements to software are ready for application.

The safety prompt is a barrier to prescribing and dispensing errors

- GP prescribing support systems provided by EMIS have been updated automatically, and no further action is required.
- Other system suppliers should apply the development changes to their systems as quickly as possible and by November 2004 at the latest. GP prescribing support systems and pharmacy dispensing systems which use the First Data Bank Europe (FDBE) Multilex Drug Data File (such as Torex, In Practice Systems, Phoenix, Boots, AAH and Hadley Healthcare[1]) will be able to request and receive FDBE updates of the required data changes and appropriate toolkit to support implementation.
- Routine updates to practices and pharmacies will therefore include the updated specification. NHS staff should ensure updates are provided to them and applied locally.
- Systems not automatically updated must be updated immediately on receipt of the disk or CD-Rom from the system supplier.

Local staff in individual GP practices or pharmacies that are not covered by the above procedures should apply the specification independently.

[1]This is not an exhaustive list, and GP practices and pharmacies should check with their system supplier.

Although a national specification for community pharmacy systems does not currently exist, it is recommended that pharmacy systems implement the NPSA specified requirements as a matter of good practice. See Appendix 2 of the NPSA report, *Towards the safer use of oral methotrexate*, listed under the resources section below.

Prescribing and dispensing systems currently in use in NHS acute trusts and local health boards in Wales must be similarly updated. The specification must be included within any new IT systems, especially those being introduced into hospitals over the next few years.

All prescribing and dispensing IT systems in primary and secondary care must be updated by March 2005.

4 Review your purchasing processes

Pfizer and Mayne Pharma have changed the shape of the 10mg tablet to help clinicians and patients distinguish it from the 2.5mg tablet. The NPSA advises NHS organisations to purchase only 10mg and 2.5mg tablets which look different from each other to avoid confusion in the future.

Resources

Visit www.npsa.nhs.uk/advice for:

A safe practice checklist developed to help NHS staff agree local actions.

The recommended patient information, the full patient safety alert, and a summary alert for use in briefing staff and for general enquires.

Towards the safer use of oral methotrexate, a background report on the NPSA's work with oral methotrexate.

Hard copies of the full alert and patient information insert are available from the Department of Health order line by telephoning 08701 555455 and quoting reference number PSA03.

Benefits

Implementing the actions above has the potential to raise awareness of the safety issues associated with the use of oral methotrexate and lead to:

- better informed and supported clinicians, in particular GPs, who assume responsibility for the majority of prescribing;
- better informed patients who understand the risks and benefits of the therapy and who share responsibility for its safe use;
- a clear clinical linkage between prescribing and monitoring to ensure patients' continued use of the drug remains safe; and
- the two strengths of the drug in easily distinguishable formats.

Next steps

Safer packaging and labelling of oral methotrexate

The NPSA is continuing to work with the pharmaceutical industry to develop safer, patient-friendly packaging.

NPSA review of actions implemented

In March 2005 the NPSA will review how the action points have been implemented through the Safety Alert Broadcast System in England. Alternative arrangements will be made for Wales. Where actions have not been implemented, the NPSA will expect the relevant strategic health authority or regional office to provide a full explanation.

The NPSA will continue to monitor patient safety incident reports made through the National Reporting and Learning System to identify any remaining causal or contributory factors.

Background

During a 10-year period (1993- 2002), the NPSA is aware of 137 patient safety incidents associated with the use of oral methotrexate which were reported to litigation agencies or described in peer-reviewed literature in England. Of these, 25 resulted in patient death and a further 26 in serious harm to the patient.

Two-thirds (67%) of these incidents involved prescribing the wrong frequency of dose of the tablets, 19% due to a lack of, or poor monitoring of therapy, and 7% because of mis-identification of the tablets by professionals or patients.

Contacts

For further details about this patient safety alert please contact the NPSA patient safety manager in your area. You can find their contact details at www.npsa.nhs.uk/static/contacts

For further information about the NPSA's oral methotrexate work, please contact:
Wendy Harris – Senior Pharmacist
National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD

Tel: 020 7927 9500
Email: wendy.harris@npsa.nhs.uk

This patient safety alert is written in the following context:

It represents the view of the National Patient Safety Agency, which was arrived at after consideration of the evidence available. It is anticipated that healthcare staff will take it into account when designing services and delivering patient care. This does not, however, override the individual responsibility of healthcare staff to make decisions appropriate to local circumstances and the needs of patients and to take appropriate professional advice where necessary.

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